Guidance for Industry and FDA

Medical Glove Guidance Manual

Draft Guidance – Not for Implementation

This guidance document is being distributed for comment purposes only.
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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Division of Small Manufacturers Assistance
Office of Health and Industry Programs

Preface

Public Comment:

Comments and suggestions regarding this draft document should be submitted by October 28th, 1999 to Docket No. 99D-2335, Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852.

Additional Copies:

World Wide Web/CDRH home page at http://www.fda.gov/cdrh/manual/glovmanl.pdf or for instructions on how to obtain this manual use CDRH Facts on Demand at 1-800-899-0381 or 301-827-0111, specify number 852 when prompted for the document shelf number.

Medical Glove Guidance[1] Manual

This document contains guidance on the basic regulatory requirements set forth in FDA's regulations that all manufacturers and importers must consider when they plan to market medical gloves. It is important to know these regulatory requirements, how to determine which ones are pertinent to your particular situation, and the proper sequence for fulfilling them. This document contains guidance on establishment registration, device listing, labeling requirements, classification, premarket notification [510(k)], medical device reporting, and good manufacturing practices of significance to manufacturers and importers of medical gloves. To the extent this guidance discusses regulatory requirements, these are requirements established by the Federal Food, Drug, and Cosmetic Act or FDA's implementing regulations in Part 800 of Title 21 of the Code of Federal Regulations. This guidance incorporates changes required by the Food and Drug Administration Modernization Act of 1997.

This document is intended to replace publication FDA 97-4257, "Guidance for Medical Gloves: A Workshop Manual" after final comments are received and incorporated.

The mention of commercial products, their sources, or their use in connection with material reported herein is not to be construed as either an actual or implied endorsement of such products by the Agency.

[1] This guidance document represents the Agency's current thinking on medical gloves. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.